Boston, United States
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23 May 2017 AEST

Meta-Analysis Show EndoBarrier Improves Glycemic Control, Induces Weight Loss in Patients with Type 2 Diabetes and Obesity

- *HbA1c: 1.3% mean reduction at explant*
- *HbA1c: 1.0% mean reduction 6 months post explant*
- *Total Body Weight: 14% mean reduction at explant*

CHICAGO — 23 May 2017 — GI Dynamics®, Inc. (ASX:GID), a medical device company that has commercialized EndoBarrier® in Europe, the Middle East and South America for patients with type 2 diabetes and obesity, today announced data from an investigator-initiated meta-analysis of 14 studies showing EndoBarrier improves glycemic control in a clinically impactful manner in patients with type 2 diabetes and obesity. According to data presented at the Digestive Disease Week (DDW) meeting in Chicago, EndoBarrier induces significant weight loss and positively affects certain digestive hormones.

Pichamol Jirapinyo, M.D., Division of Gastroenterology, Hepatology and Endoscopy at Brigham and Women's Hospital and Harvard Medical School in Boston, presented **"The effect of the duodenal-jejunal bypass liner on glycemic control in type-2 diabetic patients with obesity: a meta-analysis with secondary analysis on weight loss and hormonal changes,"** on 8 May at the DDW meeting. Dr. Jirapinyo and the study team analyzed publicly available data from 14 studies as part of the most comprehensive meta-analysis of EndoBarrier to date.

		change	# studies	# patients
HbA1c	HbA1c			
	% HbA1c Reduction	1.3%	14	431
	% Reduction	15%		
	% Reduction v Control	0.9%	4	123
	6 months post implant			
	% HbA1c Reduction	1.0%	2	99
Weight	Weight			
	Kg	12.6	10	395
	TBWL	14%		
GH	Gut Hormones			
	GIP (Hedges' g)	-0.36	5	84

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Dr. Jirapinyo and the study team used a strict methodology to determine inclusion and exclusion of the different potential clinical studies. In addition, publication bias and potential bias from large studies were accounted for. Authors were also contacted for additional data.

“This meta-analysis is very encouraging as we continue to see clinically significant reductions in HbA1c levels at 1.3% with 77% retention of the eight-month implant duration of HbA1c and month 14 (six months’ post explant). Weight loss at the time of explant is also clinically significant,” said Scott Schorer, president and CEO of GI Dynamics “This analysis further reinforces the unique method of treatment and highly differentiated clinical treatment effect of EndoBarrier.”

Meta-analysis Highlights

Primary Outcomes:

In 14 studies with a total population of 431 patients, the average decrease of HbA1c was 1.3 percent at removal of EndoBarrier, following an average implant duration of 8.4 months. Of note, in the earlier studies, EndoBarrier was implanted for 6 months while later studies extended this duration to 12 months. A subgroup analysis of four randomized controlled trials (RCTs) with a patient population of 123, saw a decrease in their HbA1c levels by 0.9% compared to the control group.

Secondary Outcomes:

Secondary outcomes in this meta-analysis measured change in weight and digestive hormones at removal and changes in HbA1c levels six months after EndoBarrier removal. Two studies with six-month data after removal of EndoBarrier showed HbA1c remained lower than baseline by 1.0%. As for weight loss, 10 studies with a total patient population of 395 patients reported average weight loss of 14.2 % and average BMI reduction of 4.2 kg/m2.

In addition, in five studies with a population of 84 patients, the meta-analysis showed a significant decrease in glucose-dependent insulinotropic peptide (GIP) at 7.8 months.

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Secondary outcomes also examined adverse events. The meta-analysis revealed 16 serious adverse events with the most common including abdominal pain, nausea and vomiting. No hepatic abscesses were found in the published studies.

Study Design

This meta-analysis reviewed published, randomized controlled trials and cohort studies found in MEDLINE, EMBASE and Web of Science through 1 Nov 2016, that assessed outcomes of EndoBarrier in patients with type 2 diabetes and obesity. Data were pooled using a mixed-effect model or a random-effect model for high heterogeneity. Of 593 potential eligible studies, 18 were included and 7 studies provided additional data.

About GI Dynamics

GI Dynamics, Inc. (ASX:GID), is the developer of EndoBarrier, the first endoscopically-delivered device therapy approved for the treatment of type 2 diabetes and obesity. EndoBarrier is not approved for sale in the United States and is limited by federal law to investigational use only in the United States. Founded in 2003, GI Dynamics is headquartered in Boston, Massachusetts. For more information, please visit www.gidynamics.com.

Forward-Looking Statements

This announcement contains forward-looking statements concerning our expectations regarding the effect of the CE mark suspension, our ability to resolve nonconformance issues to the satisfaction of our notified body, and the timing of any reinstatement of our CE mark. These forward-looking statements are based on GI Dynamics management's current estimates and expectations of future events as of the date of this announcement. Furthermore, the estimates are subject to several risks and uncertainties that could cause actual results to differ materially and adversely from those indicated in or implied by such forward-looking statements. These risks and uncertainties include but are not limited to, risks associated with obtaining funding from third parties; the consequences of stopping the ENDO trial and the possibility that future clinical trials will not be successful or confirm earlier results; the timing and costs of clinical trials; the timing of regulatory submissions; the timing, receipt and

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maintenance of regulatory approvals; the timing and amount of other expenses; the timing and extent of third-party reimbursement; risks associated with commercial product sales, including product performance, competition, market acceptance of products, intellectual-property risk; risks related to excess inventory; and risks related to assumptions regarding the size of the available market, the benefits of our products, product pricing, timing of product launches, future financial results and other factors, including those described in our filings with the U.S. Securities and Exchange Commission. Given these uncertainties, one should not place undue reliance on these forward-looking statements. We do not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information or future events or otherwise, unless we are required to do so by law.

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